

REMARKS

The present amendment is submitted in response to the Office Action mailed September 30, 2004. Claims 5-18 and 22-27 are currently pending in the application. By this amendment, independent claims 5 and 11 have been amended, and claims 18-21 have been cancelled. New claims 22-27 have been presented to recite aspects of the invention to which Applicant is believed to be entitled. In view of the amendments above and the remarks to follow, reconsideration and allowance of this application is respectfully requested.

Drawings

The objection to the drawings has been addressed in the amendment to the specification provided hereinabove.

Rejections Under 35 U.S.C. § 103

Claims 5-7, 9-14, and 16-17 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,628,732 (hereinafter Antoon, Jr. et al.) and in view of U.S. Patent No. 6,079,692 (hereinafter Powell). Antoon '732 relates to a trocar with a universal seal for use, e.g., in laparoscopic surgical procedures. Powell discloses a combination diaphragm and groove coupler seal for automatic control valves used in the water distribution industry.

It is respectfully submitted that the combination of Powell '692 with Antoon '732 is improper. More specifically, there is no suggestion or teaching in Antoon '732 to combine a fabric layer with an elastomeric layer to form a seal member having desired strength and flexibility as in the subject disclosure. Further, there is no teaching or suggestion in Powell '692 that the groove coupler-seal would be suitable for use in a surgical procedure. The groove

coupler seal receives a threaded bolt in a conventional bolt down diaphragm seal. In contrast, the seal assembly of Antoon '732 (as well as the seal embodied in the present invention) is adapted for surgical applications. The seal of Antoon '732 is adapted for repeated insertions and removals of a variety of different sized surgical objects, e.g., different sized surgical instruments, implants, etc.

Moreover, for the following reasons, the Powell '692 reference cited in the Office Action is a non-analogous art reference that cannot be combined with the disclosure of Antoon '732. In *In re Deminski*, 230 USPQ 313 (Fed. Cir. 1986), the Federal Circuit adopted a "two-step test" for determining whether particular references are within the appropriate scope of the art. First, it must be determined whether the reference is "within the field of the inventor's endeavor." Second, assuming the reference is outside that field, it must be determined whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved." With respect to the first part of the test, Antoon '732 is clearly not within the inventor's field of endeavor. The presently claimed invention is directed to an access device for performing surgery, whereas, Antoon '732 relates to water distribution systems.

With reference to the second part of the two-step test, Antoon '732 is not reasonably pertinent to the problem solved by the Applicant's. The present disclosure is directed towards seal systems used in, e.g., laparoscopic procedures, for sealingly accommodating surgical objects, e.g., including miniaturized surgical instruments of varying diameters, the surgeon's hand, etc. During such laparoscopic procedures, the body cavity is slightly pressurized. An object is inserted and advanced through the seal. The seal functions to form a substantial seal about the object during manipulation of the object (including offset manipulation) while also minimizing the passage of insufflation gas therethrough. In contrast,

Powell '692 is directed towards a diaphragm and seal for use in a water distribution pipeline system. Specifically, the diaphragm and seal of Powell '692 is used to form a flexible barrier between two chambers in order to hydraulically actuate the shut off plate to control fluid flow in the system (see Col. 3, lns. 37-45 of Powell '692). In this regard, the diaphragm and seal 10 includes a central opening to receive a rod. The rod holds the components including, e.g., pressure plates, gauges, etc. incorporated within a valve within the system.

The diaphragm in Powell forms a seal around the removable cover 50. The cover 50, and the accompanying assembly, including the diaphragm, is removable so that the gate valve may be serviced. The Powell diaphragm does not allow the introduction, removal and manipulation of objects while the seal is being maintained. By contrast, the present disclosure allows the introduction, removal and manipulation of instruments while the insufflation pressure is being maintained.

This application of Powell '692 is not reasonably pertinent to the problem the invention attempts to solve, i.e., forming a seal about a surgical object, e.g., such as a miniaturized surgical instrument which is inserted, advanced, manipulated and withdrawn through an access device. Moreover, the coupler and diaphragm seal of Powell '692 is not structurally similar to, does not operate under the same conditions and pressure as Antoon '732, and does not function in a similar manner to the surgical seal assembly of the present invention. Accordingly, a person having ordinary skill in the art would not reasonably have expected to solve a problem of forming a gas-tight seal within, e.g., an insufflated cavity of a patient by considering a reference dealing with coupling and sealing diaphragms to use in a water distribution line.

Accordingly, in view of the foregoing, withdrawal of this rejection is respectfully requested.

Claims 8 and 15 stand rejected under 35 U.S.C. §103(a) over Antoon '732 as modified by Powell '692, and further in view of U.S. Patent No. 5,350,364 (hereinafter Stephens et al.). It is respectfully submitted that Claims 8 and 15 are patentable for at least the reasons that independent Claims 5 and 11 are patentable, as discussed hereinabove. Accordingly, withdrawal of the rejection is respectfully requested.

New independent claim 24 is also believed to distinguish over the references cited in the Office Action and all of the other references of record. For example, none of the references either individually or when properly combined disclose an access device having an access housing to provide access through body tissue and to an underlying surgical site, and with a seal comprising a fabric material adapted to form a substantial sealed relation with the object.

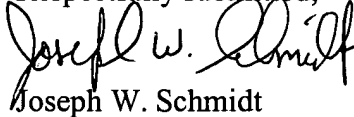
It is respectfully submitted that none of the references of record disclose or suggest the present invention as claimed in the claims as amended, considered individually or in combination, with themselves, considered in whole or in part. Accordingly, withdrawal of the rejections is respectfully requested.

In view of the foregoing amendments and remarks, reconsideration of the rejections and objections and allowance of the claims are earnestly solicited

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Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joseph W. Schmidt", written over the printed name.

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